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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/957,451  
Filing Date: September 21, 2001  
Appellant(s): SCHURR ET AL.

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Denise L. Poy  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed June 29, 2009 appealing from the Office action mailed September 9, 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

3,604,425	LE ROY	9-1971
5,620,452	YOON	4-1997

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3,032,039	BEATY	5-1962
4,246,903	LARKIN	1-1981

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 172, 174, 176, 178, 180 and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,604,425 to Le Roy in view of US 5,620,452 to Yoon.**

(claims 1, 120, 135 and 148) Le Roy discloses a clip that is fully capable of securing a fold of tissue for treating GERD, the clip comprising:

a first arm (see attached figure below);

a second arm disposed substantially opposite from each other (see figure below),

wherein the first and second arms have a first end fixedly connected to each other to define an opening that is capable of receiving a fold of tissue (see figure below)

wherein the first and second arms is capable of extending substantially in the same direction as the fold of tissue (see figure below),

wherein the opening allows tissue to extend beyond a second end of the first and second arm (see figure below),

wherein the second ends of the first and second arms are capable of maintaining a non-contacting relationship when in a deployed stated (a tissue is located between the second ends of the first and second arm which would prevent the first and second arms from contacting),

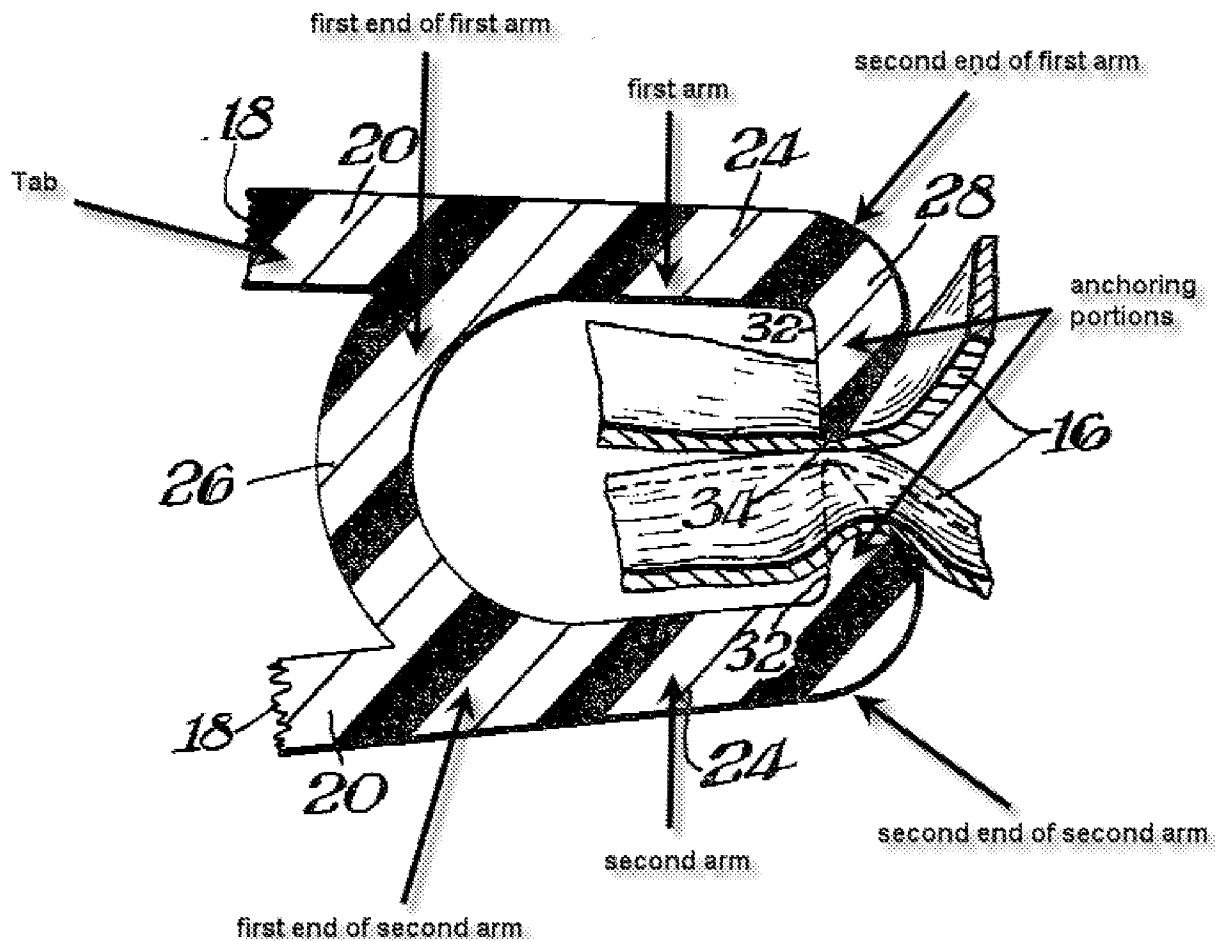
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wherein the second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in an initial, normal position (Fig. 3),

wherein the second arm **18** includes integral anchoring portions **50**, which are projections that are capable of maintaining a non-contacting relationship with the other of the first and second arms during a deployed state,

wherein the first and second arms are comprised of bioabsorbable material such that the entire clip, including the first and second arms, is capable of disintegrating in a body (col. 3, lines 40-41),

wherein the clip is fully capable of being inserted through an esophagus.



Le Roy discloses all the limitations of the claims except for the clip being made from bioabsorbable materials. However, the use of bioabsorbable materials in the manufacturing of surgical clips are well known in the art. For example, Yoon discloses a surgical clip that is made of bioabsorbable material (col. 3, ll. 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the device of Le Roy with a bioabsorbable material since it would allow the clip to dissolve in the body without requiring an additional surgery for removal. Furthermore, it would be obvious to use bioabsorbable materials in devices implanted

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within a human body since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

(claim 2) The first and second arms are fully capable of frictionally engaging an outer surface of a tissue fold.

(claims 5, 131, 144 and 154) The clip includes a gripping tab, as shown in the figure above and in Figs. 1 and 3.

(claims 7, 134, 147 and 157) The first arm and second arm forms a substantially U-shaped configuration.

(claim 121) The anchoring portion is fully capable of engaging a fold of tissue therebetween.

(claims 124, 137, 138, 150-152, 172, 174, 176 and 178) The anchoring portion is viewed as a reverse angle barb projection. As shown in the figure above, the anchoring portion is barb-like with an angle that can be viewed as reversed.

(claims 126, 127, 140, 180 and 181) The anchoring portion includes two projections that are located directly opposite to one another along the first and second arms (see figure above).

(claim 129 and 142) The additional anchoring member (either of the first and second arm) has a tip that can be called a pin that is capable of piercing tissues.

(claims 130, 143, 153) The distal end of each arm includes the anchoring portions, which tapers away from the gap.



(claims 164-167) The clip of Le Roy is fully capable of not being removed, especially after being modified to be made of a bioabsorbable material.

**Claims 132, 145, 155, 173, 175, 177 and 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le Roy in view of Yoon, as applied in the rejections above, and in view of US 3,032,039 to Beaty.**

The modified device of Le Roy discloses all the limitations of the claims except for the distal ends of the first and second arm having the tab defining a crook. Instead, Le Roy discloses tabs located in the proximal end. However, the use of tabs on a distal end of surgical clips are well known in the art, as disclosed by Beaty (see Figs. 1-3). The tabs on the distal end also allow the clips to be manipulated by an applicator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Le Roy to have the tabs be located on the distal end tabs because such arrangement is well known in the art. Furthermore, the arrangement taught by Beaty is an equivalent structure for manipulating a clip so one of ordinary skill in the art would have found it obvious to substitute a tab on the distal end for the tab on the proximal end since it would yield predictable results (both allow manipulation of the clip) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

#### **(10) Response to Argument**

With regards to the rejections to independent claim 1, the appellant argued that it would not be obvious to one of ordinary skill in the art to modify the clip of Le Roy to be made of bioabsorbable material. It was argued that Le Roy discloses a clip that is used

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solely in treating external wounds. However, this is not found persuasive as the Le Roy reference does not specify or limit that the clip is used solely for external wounds. The Le Roy reference merely states that the clip is used in "clamping wound flaps to prevent the flow of blood from severed arteries, capillaries and the like" (col. 1, ll. 11-13).

Wounds are not limited to external body surface of a patient. Wounds can also be internal, such as lacerations to the internal organs (internal wounds). Thus, the clip of Le Roy is fully capable of being used internally or externally. It should also be noted that Le Roy does state that the clip can be "applied to the two sides of wound flap (16) or other *tissue* to prevent the flow of blood from severed arteries, capillaries or the like" (col. 2, ll. 34-37). This clearly shows that the clip is not limited for use with the patient's skin. Furthermore, in the Advisory Action mailed on 2/6/09, the examiner has provided the Larkin reference which clearly shows that "hemostatic clips" are used internally for closing internal wounds.

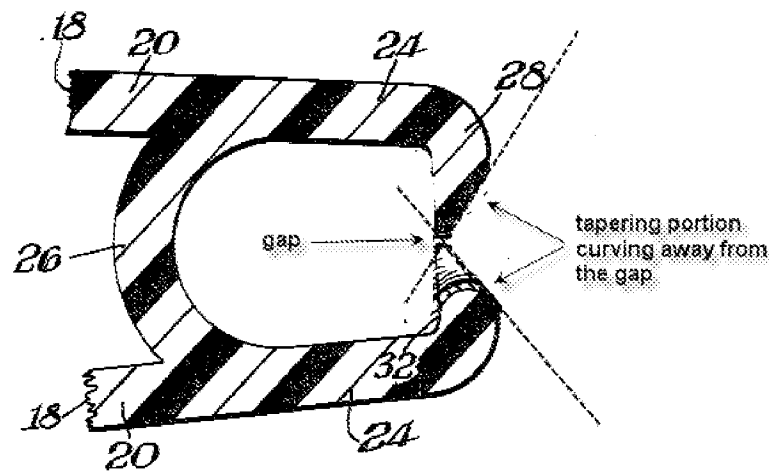
Therefore, one of ordinary skill in the art would have found it obvious to modify the clip of Le Roy to be made of bioabsorbable materials, as disclosed by Yoon, because when used in treating internal wounds, it would allow the clip to dissolve in the body without requiring an additional surgery for removal.

With regards to the rejections of claims 129 and 142, the appellant argued that Le Roy fails to teach the limitation of "an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold". It was argued that the tip portion 34 of Le Roy is disclosed to be rounded or blunt. However, it is the examiner's position that the tapered tip portion 34 of Le Roy is fully capable of piercing

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tissue when enough force is applied to the clip. For example, a pen has a rounded or blunt tip, but it can also be used to penetrate a skin surface when enough force is applied.

With regards to the rejections claims 130, 143 and 153, the appellant argued that Le Roy fails to teach the limitation “the distal end of one of the first and second arms includes a tapering portion curving away from the gap. The Examiner is reproducing Fig. 5 below to show how Le Roy discloses a tapering portion that curves away from the gap. As illustrated below, the tip portion 34 includes a tapering portion that tapers away from the gap.



With regards to the rejections of claims 174 and 178, the appellant argued that Le Roy fails to teach the limitation of “the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue”. As noted in

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the response to the rejections to claims 129 and 142 above, the Examiner is interpreting the tip portion 34 of Le Roy as the barb structure. The tapered tip portion 34 of Le Roy is fully capable of piercing tissue when enough force is applied to the clip.

With regards to the rejections to claims 132, 145, 155, 173, 175, 177 and 179, the appellant argued that it would not be obvious to modify the clip of Le Roy to have "a gripping tab...located at the distal end of one of the first and second arms" or one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion".

Le Roy discloses gripping tabs 18 on the proximal end of the clip. However, as recited in the rejections above, it is well known in the art for clip delivery devices to interact with either the proximal end of a clip or the distal end of a clip for manipulating the shape of the clip. While Le Roy discloses a clip having gripping tabs located on the proximal end of the clip, Beaty discloses a clip having gripping tabs 14/16 located on the distal end. Both perform the same function of allowing a clip applicator to manipulate the shape of the clip. Therefore, a simple substitution of the gripping tab of Le Roy for the gripping tabs of Beaty will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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